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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/08/98	08/27/98	KELLY	85010340301

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HM11/1222

EXAMINER

GUPTA, A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/22/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



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EXAMINER

ART UNIT

PAPER NUMBER

8

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 Months from the date of this letter.
Failure to respond within the time period will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENTS ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-6 are pending in the application.
Of the above claims, _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1, 3-6 are rejected.
5. ☒ Claims 2 are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____ has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under 35 USC 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. ____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

09/043,813

DETAILED ACTION

1. Claims 5-6 are objected to under 37 C.F.R. § 1.75 as being in improper form because a multiple dependent claim should refer to other claims in there alternative and cannot depend on any other multiple dependent claim. See M.P.E.P. § 608.01(n).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerard et al.

2. The claims are drawn to a peptide that has the sequence cyclo (Val-Orn-Leu-D-Tyr-Pro-Phe-D-Phe-Asn-Asp-Trp).

Gerard et al. teach the peptide cyclo(Val-Orn-Leu-D-Tyr-Pro-Phe-Phe-Asn-Asp-Trp) that inhibited growth of Staphylococcus aureu, Enterococcus sp. and Streptococcus pneumonia (see page7202 and 7204). The reference further teach that the a GC analysis confirmed the presence of a L-Val, L-orn, L-leu, L-try, L-pro, L-phe, D-phe, L-trp, L-asg (see apge 7202).

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerard et al. in view of Paradies.

The claims are drawn to a peptide that has the sequence cyclo (Val-Orn-Leu-D-Tyr-Pro-Phe-D-Phe-Asn-Asp-Trp).

Gerard et al. teach the peptide cyclo(Val-Orn-Leu-D-Tyr-Pro-Phe-Phe-Asn-Asp-Trp) that inhibited growth of Staphylococcus aureus, Enterococcus sp. and Streptococcus pneumonia (see page 7202 and 7204). The reference further teaches that a GC analysis confirmed the presence of a L-Val, L-orn, L-leu, L-try, L-pro, L-phe, D-phe, L-trp, L-asn (see page 7202). The difference between the prior art and the instant application is that the reference does not teach a pharmaceutical formulation for the peptide.

However, since Gerard et al. teach that the peptide has biological activity, it would have been obvious to one of ordinary skill in the art to formulate the peptide in a pharmaceutical formulation, as taught by Paradies et al., so as to achieve antimicrobial activity in-vivo.

4. Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerard et al. in view of Paradies and in further view of Buckley et al. and Dayhoff et al.

The claims are drawn to a peptide that has the sequence cyclo (Val-Orn-Leu-D-Tyr-Pro-Trp-D-Phe-Asn-Asp-Trp).

The reference of Gerard et al. and Paradies et al. have been discussed supra. The difference between the prior art and the instant application is that the peptide of the prior art teaches a L-Phe residue at the 6th position while the claims claim a L-Trp residue at the 6th position.

Both Buckley et al. and Dayhoff et al. teach that the amino acid Phe and Trp form an exchange group both contain Aromatic rings, are hydrophobic, and large (see page 96 in Dayhoff and figure 1 in Buckley et al.). Therefore it would have been obvious, when searching for new analogs, to substitute Trp for Phe in the peptide because one would expect a peptide containing a Trp residue to have similar activity to the native peptide since a Trp and Phe substitution is a conservative substitution.

5. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The claims is drawn to a peptide that has the sequence (Val-Orn-Leu-D-Tyr-Pro-Trp-D-Phe-Asn-Asp-Tyr). The closest prior art of Gerard et al. does not teach nor suggest the claimed peptide since the peptide of the prior art differs from the claimed peptide in two amino acids.

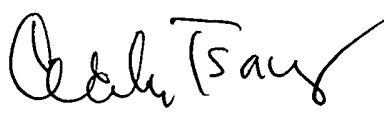
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (703) 308-0254. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Anish Gupta



Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600